SUBJECT: Coding of Clinical Research Data under the caBIG™ Program	SOP No.: CR-006
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Standard Operating Procedure – Coding of Clinical Research Data under the caBIG™ Program

This cover sheet controls the layout and components of the entire document.

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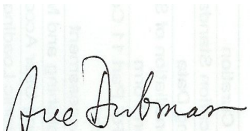
Department Approval:



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QA Approval:

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Note: This document will be issued for training on the Issue Date. The document will become available for use to trained personnel on the Effective Date. Before using this document, make sure it is the latest revision. Access the caBIG™ website to verify the current revision.

Revision History

Revision	Date	Author	Change Reference	Reason for Change
1.0	09/19/2005	SOP Working Group	N/A	Initial release.

1. Purpose

This Standard Operating Procedure (SOP) describes the process for coding of clinical research data (e.g., Adverse Events, medications, patient medical history, medical procedures) to ensure that coding terms and information data are captured in an effective and consistent manner to facilitate meaningful interpretation and analysis.

2. Scope

This SOP applies to all clinical trial research studies sponsored by the National Cancer Institute (NCI) and within the caBIG™ Program.

3. Requirements

3.1 Dictionary version information should be captured in the study plan for the clinical research trial.

3.2 A formal procedure should be established for evaluating a change in a dictionary or version.

3.3 The dictionary is selected, reviewed, loaded, tested and released into production in conjunction (along with) the clinical research trial for study conduct.

3.5 All individuals involved in the coding, analyzing and reporting of coded data should be appropriately trained on the functionality and capabilities of the coding dictionaries used.

3.6 Any requests for modification of the dictionary (e.g., added terms, modified terms) should be made known to the dictionary group.

3.7 Changes or updates to the dictionary must be approved by the dictionary group and the clinical research study team conducting the trial.

4. References /Regulations/Guidelines

Section	SOP Number	Title
4.1	CR-001	SOP for Study Set Up
4.2	CR-002	SOP for Study Conduct

5. Roles & Responsibilities

Role	Responsibility
Study Coordinator	• Select the dictionary for coding terms collected during the clinical research trial. • Work with the Coding Specialists and/or the Drug Safety Officer (when appropriate) to assign dictionary codes to no-match terms.
Coding Specialist	• Work with clinical study personnel and, when applicable, the Drug Safety Officer on coding of clinical research data.
Drug Safety Officer	• Work with Coding Specialist and Clinical Data Managers to resolve coding issues for Adverse Events.
Study Designer	• Manage the loading of the select dictionary into table format within the clinical data management application.

6. Attachments

This SOP will be used in conjunction with the following attachments. These attachments must be used by all research sites conducting clinical trials under the caBIG™ Program and can be customized by individual research sites to accommodate format and content in accordance with local guidelines and/or requirements.

Title	Description
1) Procedure Description for Coding of Data	This document provides instructions for coding of data, it provides step-by-step guidance to ensure that all data are coded in a consistent manner.
2) Process Flow for Coding of Data	This process flow provides a visual guide outlining the individual steps that need to be completed in order to code specific data.